

and Applicant's attorney of record, William E. Jackson, during a personal interview on January 24, 2002.

I. BACKGROUND

The Applicant's attorney wishes to thank the Examiner for the courtesy of allowing a personal interview on January 24, 2002. The present amendment has been prepared based upon the discussions during the interview. The "Interview Summary" prepared by the Examiner at the end of the interview indicates that it is not necessary for the Applicant to provide a separate record of the substance of the interview. However, pertinent comments are made about the interview as discussed below.

During the interview, the marked-up replacement claim 1 was extensively discussed. As indicated in the Examiner's record of the interview, the Examiner agreed that the replacement claim would overcome the rejections under §112. Similarly, the presently proposed marked-up replacement claim for claim 17 generally parallels the marked-up replacement claim 1 and should overcome the rejections under §112 for the same reasons discussed with reference to replacement claim 1.

At the interview, Applicant's attorney advised the Examiner that there were a number of dependent claims that had not been rejected based upon prior art and that they should therefore be in condition for allowance. Specifically, dependent claims 6, 7, 10-14, 22-23 and 25-27 were not rejected based upon prior art and would be allowable if not subject to further rejection under §112. However, the Examiner indicated that it was his desire to conduct further search of the prior art with respect to these dependent

claims. Because of the final rejection status of this application, Applicant has filed a Request for Continued Examination under 35 U.S.C. §132(b).

At the interview, the Examiner suggested that in preparing a response to the outstanding Office Action in the form of a continuing application that a claim be submitted that includes the specific identification of the identity of the insect repellent and other additives with the specific preferred ranges also included for each of them. Accordingly, new claim 30 has been drafted pursuant to these discussions at the interview and is proposed for examination in this RCE.

II. FURTHER RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. §112

As reflected in the Examiner's interview record, the Examiner raised the issues of operability of the claim combination of wax and insect repellent. In particular, the Examiner indicated that he desired empirical data that the disclosed levels of repellent (.5 to 6.0%) in fact worked rather than being hypothetical. The Examiner indicated that he would be satisfied with a declaration outlining the empirical data in lieu of a continuation-in-part adding pertinent empirical data to the disclosure.

To comply with the Examiner's request for empirical data or the like, concurrently filed herewith is a declaration under 37 CFR §1.132 ("Rule 132 Declaration") of Ms. Veronica Townsend, formerly Veronica Robinson, the present invention. It is respectfully submitted that the extensive declaration of Ms. Townsend including the associated documentation fully comply with the Examiner's request for data to show that the disclosed levels of repellent in fact worked and were non-toxic to the user. It is also respectfully submitted that the declaration provides sufficient information to point out

how the insect repellent is present in an amount that is effective and yet still non-toxic to the user.

Applicant's original claims 1-27 were rejected in the first Office Action under 35 U.S.C. §112, second paragraph, as being indefinite because of the phrases "the like" and "mild". The phrase "the like" appeared in all of the original claims while the phrase "mild" was found in claims 6 and 22. In applicant's response to the first Office Action, these phrases were deleted. The second Office Action did not reject any claims based upon 35 U.S.C. §112, second paragraph. Applicant respectfully submits that the proposed amendments are definite and that the amended claims comply with §112, second paragraph.

Applicant's original claims 1-27 were rejected in the first Office Action under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skill in the art to make the invention. Specifically, the Examiner alleged that "the invention would not be within the skill of one in the art to produce, without providing toxicity to the wearer, as the invention requires contact with known irritants and neurotoxic poisons "pyrethrum, canida, for example, p. 136, 137)." The Examiner also asserted that "absent identification of ingredients, ratios, and concentrations, one would not be able to identify how to repel what pest, for how long, without hurting host, or being ineffective."

In response to this rejection, the applicant amended independent claims 1 and 17 to clarify that the repellent is present in an amount sufficient to treat and prevent infestations of lice and other parasitic insects to a user. Applicant also amended the claims to clarify that the repellent is present in an amount that is non-toxic to the user.

Specification support for these amendments was identified at page 6, line 23 to page 7, line 29 and page 8, lines 2-5.

In the second Office Action, claims 1-29 are rejected under 35 U.S.C. §112, first paragraph, with the Examiner asserting that "the rejection of record is maintained. This invention requires continuous contact with the skin, thus the limitations requested are seen as critical elements in accord with the invention as disclosed. (See p. 6, lines 23-29, p. 7, lines 2-5.) These pages indicate the ingredients and percent, and show them as toxic." A review of the disclosure cited by the Examiner reveals that the specification discloses the amount (0.5% to 6.0% by volume) of pyrethrum sufficient to kill any lice or nits present. However, contrary to the Examiner's above-quoted statements, the applicant does not state that pyrethrum in the range is toxic to a person. In fact, the specification discloses the opposite, specifically that the "naturally occurring repellents employed are less hypo-allergenic and more environmentally friendly than the prior art synthetic compounds" (page 9, lines 6-15).

It is respectfully submitted that the claims as now amended clarify that the amount of repellent is sufficient to treat or kill lice and other parasitic insects while being non-toxic to the person whose skin or hair is contacted. Moreover, dependent claims 9 (and its dependent claims 10-14) specifically recite that the "carrier composition includes between 0.6 to 6% by volume of pyrethrum." Thus, applicant submits that these claims expressly obviate or meet the Examiner's criticisms under §112, first paragraph. Accordingly, the rejections should be withdrawn.

The second Office Action has newly rejected claims 1-29 under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification. The

Examiner has asked that the non-toxic phrase be removed or modified to be in accord with the specification. As discussed above, the amended claims obviate this rejection because they clarify that the insect repellent is present in an amount that is non-toxic to a person but sufficient to prevent infestation of lice..." This is clearly disclosed at page 5, lines 27-33 ("Pyrethrums are noted for the very rapid paralysis (knock-down) effect produced on flies, mosquitoes and other insects") and page 9, lines 13-15 ("the naturally occurring repellents employed are less hypo-allergenic...than the prior art synthetic compounds").¹

In view of the interview, the claim amendments and Ms. Townsend's declaration, reconsideration and allowance are requested.

III. RESPONSE TO REJECTIONS UNDER 35 U.S.C. §§102, 103

The second Office Action relies upon Page, Bartlett, Gates, Newman, Tucci and Metzner under §§102, 103. Applicant respectfully traverses the rejections for the reasons given below. In sum, none of the references, taken singly or in combination, describes the claimed subject matter. With regard to the prior art rejections, Applicant's attorney explained at the interview that the claimed inventions involved a wax-to-repellent concentration which is a substantially high proportion and that none of the cited references showed or taught such a high proportion. Further, it was pointed out that the references tended to disclose the opposite, namely, high proportions of repellent and low proportions of wax or wax-like substance. The deficiencies of the references are discussed in detail below.

¹ "Hypo-allergenic" is defined as "having a relatively low capacity to induce hypersensitivity." Webster's Third New International Dictionary.

Independent claims 1 and 17 have been amended so as to clarify that although the carrier composition is solid at room temperature, the wax and insect repellent are present in proportions which ensure that the carrier composition softens when at a temperature corresponding to the body temperature of a person. This is significant since, when the garment incorporating the insect repellent substrate is worn by a person such that the insect repellent substrate is in contact with hair or skin of the person, the person's body heat causes the carrier composition to soften to thereby provide a controlled release of the insect repellent from the fabric base material to the hair or skin of the person. There does not appear to be any disclosure of this arrangement in any of the newly-cited references relied upon in the Office Action.

A significant aspect of the present invention is that a repellent carrier composition is provided which includes a mixture of wax and an insect repellent, the wax being present in a substantial proportion by volume (e.g., see claims 28 and 29 - 76% wax) so that the carrier composition solidifies at room temperature and thereby inhibits release of the insect repellent, and so that the composition softens when at body temperature so as to provide a controlled release of the insect repellent when in contact with a person's hair or body. Accordingly, when a garment incorporating the insect repellent substrate is removed, the composition hardens thereby inhibiting further release of the active constituents.

In U.S. Patent No. 246,355 (Page), there is disclosed a composition for protecting fabrics and the like from moths, vermin, etc., which includes 5-10% of paraffin wax and 90-95% of naphthalene impregnated into a fabric. Column 2, lines 68-77 discloses potential uses of the impregnated fabric as a lining for boxes, trunks, etc., so

as to protect woolens, furs, etc., disposed in the boxes or trunks from moths, vermin, etc.

However, because of the high proportion of naphthalene and low proportion of wax in this composition, release of the insect repellent (naphthalene) from this composition will not be inhibited when the composition is at room temperature and, since this composition will not soften at body temperature, release of the insect repellent would not be enhanced by body temperature should the impregnated material be worn by a person.

Accordingly, the composition disclosed in Page is totally unsuitable for the presently-claimed use since there is no mechanism for changing the rate of release of insect repellent depending on whether the impregnated fabric is being worn by a person and therefore at body temperature or not. Indeed, since Page is directed to impregnated fabrics for use in lining boxes, trunks, etc., there is no reason to suggest that a person of ordinary skill in the art would modify the teaching of Page to arrive at an impregnated fabric wherein the release rate of insect repellent depends on whether a garment to which fabric is attached is brought to body temperature when worn by a person or not.

The disclosures in the Bartlett, Gates and Newman patents are considered to be even less relevant to the presently-claimed invention than Page since each of these patents discloses insect repellents which may either be applied directly to human skin or impregnated into a fabric so as to afford effective protection against insect bites. However, although each of these documents discloses mixing an insect repellent compound with a solid carrier, and impregnating an insect repellent into a fabric, these

are discussed as separate application methods. In a first application method, a solid carrier mixed with an insect repellent is applied to a person's skin (for example as a gel or cream). In a second application method, the insect repellent alone is impregnated into a fabric using an inert solvent. There is no disclosure of impregnating an insect repellent mixed with a wax into a fabric. In any case, even if these two application methods could be read together, the presently-claimed invention would still not be arrived at since the solid carrier discussed in these patents is petrolatum which is a petroleum jelly. This compound would not serve to inhibit release of insect repellent when at room temperature and would not increase release of insect repellent when at body temperature.

In U.S. Patent No. 6,015,570 (Tucci), there is disclosed a slow release insect repellent composition for use with fabric substrates of garments. In Example V in column 8, there is reference to combining an insect repellent composition with a wax emulsion. However, the wax emulsion is present only in a relatively small proportion (6%) and is referred to in column 2, lines 53-56 as a finishing agent. There is no disclosure of providing a composition including wax and an insect repellent which inhibits release of insect repellent when at room temperature and which increases release of insect repellent when at body temperature.

In U.S. Patent No. 4,862,832 (Metzner), there is disclosed a dispenser for the application of insecticides to the surface of animals wherein bristles of a dispenser are coated with an active component. When the bristles are glided through the coat of an animal, a composition including the active component comes off (column 2, lines 24-31). Although the document states that a wax such as beeswax may be used in the

composition, there is no disclosure of providing a composition which is arranged to inhibit release of insecticide when at room temperature and increase release of insecticide when at body temperature. Moreover, this patent does not disclose impregnating a fabric with an insect repellent; the insect repellent in this patent is merely disposed on the surface of bristles of a comb, brush, etc.

Favorable reconsideration and allowance is respectfully requested. If the Examiner believes that a telephone conference will advance this case to allowance, he is requested to contact the undersigned attorney.

Respectfully submitted,

Date: July 18, 2002

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ATTACHMENT B

Marked Up Replacement Claims

Following herewith is a marked up copy of each rewritten claim.

1. (Twice Amended) An insect repellent substrate for repelling lice and other parasitic insects and for attachment to a garment to be worn by a person, the substrate comprising:

a strip of fabric base material impregnated with a repellent carrier composition, the carrier composition being solid at room temperature, the strip being adapted to attach to the garment in a manner that will ensure continuous contact of the insect repellent substrate with the wearer's hair or body, the carrier composition including a mixture of wax and an insect repellent in proportions such that the carrier composition softens when at a temperature corresponding to the body temperature of a person, the insect repellent being present in a non-toxic amount that is non-toxic to a person but sufficient to treat and prevent infestations of lice and other parasitic insects on a user person whereby, in use, when the garment is worn by a person such that the insect repellent substrate is in contact with hair or skin of the person, the wearer's person's body heat causes the carrier composition to soften to thereby provide a controlled release of the insect repellent from the fabric base material to the hair or skin of the person.

17. (Twice Amended) A method of manufacturing an insect repellent substrate for repelling lice and other parasitic insects for attachment to a garment to be worn by a person, the method comprising:

producing a repellent carrier composition by

heating a wax to a liquid state, and

mixing an insect repellent with the liquid wax to form a mixture;

the wax and insect repellent being in proportions such that the carrier composition is solid at room temperature and softens when at a temperature corresponding to the body temperature of a person;

dipping a strip of fabric base material into the carrier composition while still in the liquid state for a sufficient length of time to allow the base material to absorb some of the carrier composition and such that the insect repellent is present in ~~a non-toxic an amount that is non-toxic to the person but sufficient to treat and prevent infestations of lice and other parasitic insects on a user person~~;

allowing the impregnated strip of base material to cool so that the carrier composition solidifies on the base material to form said insect repellent substrate; and,

attaching the substrate to the garment in a manner that will ensure continuous contact of the insect repellent substrate with the ~~wearer's hair or body of a wearer of the garment, whereby, in use, when the garment is worn by a person such that the insect repellent substrate is in contact with hair or skin of the person, the wearer's body heat causes the carrier composition to soften to provide a controlled release of the insect repellent from the fabric base material to the hair or skin of the person.~~